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**To:** "Martha M. Rumore" <mrumore@frierlevitt.com>, Charles Boyd <CharlesB@Safechain.com>  
**Subject:** RE: BIKTARVY Lots CCZCFA & CDFYCA  
**Attachment:** LOT CCXKVA PACKAGING SLIP INVOICE T3 INFO ORDER 2678 (002).pdf  
**Attachment:** PED.01I29926 lot CCXKVA.pdf  
**Attachment:** T3 from Gentek LOT CCZCFA.pdf

Hi Martha,

I have attached the requested documents. We have the bottle of Biktarvy (lot CDFYCA) from Medicine Shoppe which contains what we think is the Seroquel here in quarantine, we were never instructed what we should do with it, and will not accept this lot should we received it.



**Abbie Divilio** | Director of Compliance  
Safe Chain Solutions, LLC  
822 Chesapeake Drive | Cambridge, MD 21613  
office: 855.437.5727 x1017 | fax: 866.930.1128  
[www.SafeChain.com](http://www.SafeChain.com) |

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**From:** Martha M. Rumore <mrumore@frierlevitt.com>  
**Sent:** Friday, February 19, 2021 1:36 PM  
**To:** Charles Boyd <CharlesB@Safechain.com>  
**Cc:** Abbie Divilio <AbbieD@Safechain.com>  
**Subject:** FW: BIKTARVY Lots CCZCFA & CDFYCA

Hi Charlie and Abbie:

I have received two separate communications from Peter Colosi of Gilead regarding the product complaint we submitted for the bottle of Lot # CCZCFA (assigned PR#213279 by Gilead's QC Department). Mr. Colosi is additionally requesting the copy of the T3 document you received from Gentek so they can see the authorized distributor that Gentek purchased from. He is also asking for a copy of all communications with Gentek regarding this matter and Gentek's contact information as they will need to follow up directly with Gentek. Let me know if you are willing to provide them with the T3? They can just find the authorized distributor themselves since we sent the serial number we provided.

Mr. Colosi is further requesting a response to his Dec 10<sup>th</sup> letter regarding lots CCXKVA and requesting the T3 data which Safe Chain did not want to supply at the time b/c of confidentiality. Has this changed- are you willing to supply the T3 here?

In the second communication I received (see below), Mr. Colosi refers to another incident which Medicine Shop stated they reported to Safe Chain in October 2020, involving lot #CDFYCA (contained

GOVERNMENT  
EXHIBIT

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1:24-cr-20255-WPD

Seroquel). He is requesting the T3 document for that case. He indicated that Medicine Shop reported they never heard back. My records indicate something contrary to Mr. Colosi's assertions. As I recall, the incident was reported to Gilead's QC Dept, the bottle was sent to Gilead from the pharmacy, and it was assigned PR#196084 by Gilead's QC Department. You in fact, never heard back from Gilead. Please let me know if this is correct as I would like to respond to this assertion as well.

As you can see from Mr. Colosi's correspondence, Gilead has turned from investigating your product complaint to accusatory. No surprise here. Please let me know how you wish to respond. I am free for a call today after 3:30 pm or on Monday if you would rather speak.

Best,

Martha

Martha M. Rumore, PharmD, MS, JD, LLM  
*Senior Counsel*



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**From:** Peter Colosi <[peter.colosi@gilead.com](mailto:peter.colosi@gilead.com)>  
**Sent:** Thursday, February 18, 2021 8:07 PM  
**To:** Martha M. Rumore <[mrumore@frierlevitt.com](mailto:mrumore@frierlevitt.com)>  
**Cc:** Lori Mayall <[Lori.Mayall@gilead.com](mailto:Lori.Mayall@gilead.com)>  
**Subject:** RE: BIKTARVY Lots CCZCFA & CDFYCA

[EXTERNAL SENDER: This message came from an EXTERNAL address. DO NOT click on links or attachments unless you know the sender and the content is safe.]

Martha –

I'm going to be out of the office tomorrow. I'm copying my colleague, Lori Mayall, who is familiar with these matters. Her cell is 650.474.1221 should you need to talk to us tomorrow.

Pete Colosi (he/him/his)  
415-341-3818

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**From:** Peter Colosi  
**Sent:** Thursday, February 18, 2021 8:35 AM  
**To:** Martha M. Rumore <[mrumore@frierlevitt.com](mailto:mrumore@frierlevitt.com)>  
**Subject:** BIKTARVY Lots CCZCFA & CDFYCA

Hi Martha –

First, did you ship the BIKTARVY® Lot CCZCFA bottle to Gilead at my attention? I'm not in the office now, but if so, I can route that bottle to the right people. If you didn't ship the bottle, did you ship something else? I received a FedEx tracking notification that appears to reference or originated at Safe Chain.

Second, in addition to my request yesterday for the DSCSA Document related to Lot CCZCFA and all communications with Gentek, we received information from Medicine Shoppe (the pharmacy that purchased Lot CCZCFA from Safe Chain) about another bottle of BIKTARVY that contained foreign tablets. Medicine Shoppe told us that in Oct. 2020 it purchased a bottle of BIKTARVY Lot CDFYCA that contained Seroquel tablets from Safe Chain. Medicine Shoppe stated that it informed Safe Chain but never heard anything back.

Can Safe Chain please provide us with any and all information relating to this Lot as well? We'll need a DSCSA Document showing the supply chain for this lot, the bottle of BIKTARVY returned to Gilead if possible, and any information that Medicine Shoppe would have shared with Safe Chain about the complaint or images of this bottle.

Thank you. Please let me know if you have any questions.

Pete Colosi (he/him/his)  
415-341-3818



# DSCSA TRACEABILITY REPORT

**AUTHORIZED BY:** EDEL REYES  
**POSITION:** COMPLIANCE MANAGER

 <b>GENTEK</b>		<b>ITEM NUMBER: 2501</b>	<b>NDC # 61958-2501-1</b>	<b>BIKTARVY, TAB 50/200/25MG (30/BT)</b>		
DATE: 7/28/2020		INVOICE: 2678	PO: 4/4/5210	MFG : GILEAD SCIENCE		
CONTACT BUYER: ADAM BROSUS		EMAIL: ADAM@PHARMASALES.COM	CONTACT SELLER: EDEL REYES	EMAIL: <a href="mailto:SALES@GENTEKUSA.COM">SALES@GENTEKUSA.COM</a>		
TYPE	INVOICE/DATE	QTY	SELLER:	SHIPPED FROM:	SOLD TO:	SHIPPED TO:
TI	2678 7/28/20	272	GENTEK LLC 203-274-3527	45 CEDAR ST UNIT 3 , STAMFORD , CT 06902	SAFE CHAIN SOLUTIONS 215-595-3932	822 CHESAPEAKE DRIVE ,CAMBRIDGE,MD 21613
TH	851011 7/23/20		DROGUERIA BETANCES 939-488-2018	LUIS MUNOZ MARIN AVE,ESQ. EL TROCHE, CAGUAS, PR 00725	GENTEK LLC 203-274-3527	45 CEDAR ST UNIT 3 , STAMFORD , CT 06902
TH	114172 7/15/20		GILEAD SCIENCE MANUFACTURER	1800 WHEELER AVENUE #A VERNE , CA 91750	DROGUERIA BETANCES 939-488-2018	LUIS MUNOZ MARIN AVE,ESQ. EL TROCHE, CAGUAS, PR 00725

(LOT NUMBERS)

"TS: Seller has complied with each applicable subsection of FDCA Sec. 581 (27)(A)-(G).

**For Questions regarding your DSCA report or to authenticate a subsequent transaction, please contact [SALES@GENTEKUSA.COM](mailto:SALES@GENTEKUSA.COM).**

# Drug Supply Chain Security Act Document Doc#00000014606

## (TI) Transaction Information

Drug Name, Strength, Dosage Form, Container Size: BIKTARVY 30CT, 50/200/25 MG NDC: 61958-2501-01			Reference Number: <u>01I29926</u>
Lot Number	Quantity	Unique Serial #	Document Type: <u>Invoice</u>
CCXKNA	2		Reference Date: <u>07/29/20</u>
CCXKPA	4		
<b>CCXKVA</b>	2		

## (TH) Transaction History

Manufacturer's Name: GILEAD SCIENCES, INC  
 Manufacturer's information: 333 LAKESIDE DRIVE FOSTER CITY, CA 94404

SOLD TO: Name: DROGUERIA BETANCES Address: LUIS MUNOZ MARIN AVE CAGUAS PR 00725 Date Purchased & Ref : 07/15/20 114172	SHIPPED TO: Name: DROGUERIA BETANCES Address: LUIS MUNOZ MARIN AVE CAGUAS PR 00725 Date Received & Ref : 07/15/20 114172
SOLD TO: Name: GENTEK LLC Address: 45 CEDAR ST UNIT 3 STAMFORD CT 06902 Date Purchased & Ref : 07/23/20 851011	SHIPPED TO: Name: GENTEK LLC Address: 45 CEDAR ST UNIT 3 STAMFORD CT 06902 Date Received & Ref : 07/23/20 851011
SOLD TO: Name: SAFE CHAIN SOLUTIONS, LLC Address: 822 CHESAPEAKE DR CAMBRIDGE MD 21613 Date Purchased & Ref : 07/28/20 PO#01209048	SHIPPED TO: Name: SAFE CHAIN SOLUTIONS Address: 822 CHESAPEAKE DR CAMBRIDGE MD 21613 Date Received & Ref : 07/29/20 RC#013308
SOLD TO: Name: WHITE CROSS PHARMACY - BRAWLEY Address: 1222 W 5TH ST SAN BERNARDINO CA 92411 Date Purchased & Ref : 07/29/20 01S27133003	SHIPPED TO: Name: WHITE CROSS PHARMACY Address: 602 MAIN ST BRAWLEY CA 92227 Date Received & Ref : 07/29/20 01S27133003
SOLD TO: Name: Address: Date Purchased & Ref :	SHIPPED TO: Name: Address: Date Received & Ref :

(TS) Transaction Statement: This Company complied with each applicable subsection of FDCA Sec. 581 (27) (A) – (G)

- (A) is authorized as required under the Drug Supply Chain Security Act;
- (B) received the product from a person that is authorized as required under the Drug Supply Chain Security Act;
- (C) received transaction information and a transaction statement from the prior owner of the product, as required under section 582;
- (D) did not knowingly ship a suspect or illegitimate product;
- (E) had systems and processes in place to comply with verification requirements under section 582;
- (F) did not knowingly provide false transaction information; and
- (G) did not knowingly alter the transaction history.



# DSCSA TRACEABILITY REPORT

**AUTHORIZED BY:** EDEL REYES  
**POSITION:** COMPLIANCE MANAGER

 <b>ITEM NUMBER: 2501</b>		NDC # 61958-2501-1		BIKTARVY, TAB 50/200/25MG (30/BT)	
DATE: 10/26/2020		INVOICE: 2736		PO: 01210349	MFG : GILEAD SCIENCE
CONTACT BUYER: ADAM BROSUS		EMAIL: ADAM@PHARMASALES.COM		CONTACT SELLER: EDEL REYES	EMAIL: <a href="mailto:SALES@GENTEKUSA.COM">SALES@GENTEKUSA.COM</a>
TYPE	INVOICE/DATE	QTY	SELLER:	SHIPPED FROM:	SOLD TO:
TI	2736 10/27/20	156	GENTECK LLC 203-274-3527	45 CEDAR ST UNIT 3 , STAMFORD , CT 06902	SAFE CHAIN SOLUTIONS 215-595-3932
TH	85199 10/26/20		DROGUERIA BETANCES 939-488-2018	LUIS MUNOZ MARIN AVE,ESQ. EL TROCHE, CAGUAS, PR 00725	GENTECK LLC 203-274-3527
TH	114369 10/21/20		GILEAD SCIENCE MANUFACTURER	1800 WHEELER AVENUE LA VERNE , CA 91750	DROGUERIA BETANCES 939-488-2018
LUIS MUNOZ MARIN AVE,ESQ. EL TROCHE, CAGUAS, PR 00725					

(LOT NUMBERS)

LOT	EXP DATE	QTY	LOT	EXP DATE	QTY	LOT	EXP DATE	QTY	LOT	EXP DATE	QTY
CCVDCA	05/31/2021	1	CDFYHA	09/30/2022	12						
CDFYFA	09/30/2022	8	CDMHCA	11/30/2022	2						
CDGWYA	09/30/2022	4	CDFYCA	09/30/2022	4						
(blank)			CDGXFA	10/31/2022	4						
CDMHDA	12/31/2022	8	CDGWZA	10/31/2022	4						
CDMGXA	11/30/2022	7	CDGXCA	10/31/2022	1						
CDFXZA	09/30/2022	5	CDMHFA	12/31/2022	4						
CDGXGA	10/31/2022	4	CDGXBA	10/31/2022	3						
CDMGTA	10/31/2022	8	022058	12/31/2022	1						
6400501A	09/30/2022	1	CDMHBA	11/30/2022	2						
CDFYBA	09/30/2022	2	6400503A	09/30/2022	2						
CDMGZA	11/30/2022	11	CCZCCA	08/31/2022	1						
CDSDZA	12/31/2022	10	CDMGWA	10/31/2022	3						
CDGXDA	10/31/2022	2	CCZCFA	08/31/2022	2						
022054	11/30/2022	7	6341502A	06/30/2022	1						
CDGXKA	10/31/2022	4		Grand Total	156						
CDMGSA	10/31/2022	11									
CDGXHA	10/31/2022	12									
CDSDYA	11/30/2022	4									
6341503A	06/30/2022	1									
										GRAND TOTAL	156

"TS: Seller has complied with each applicable subsection of FDCA Sec. 581 (27)(A)-(G).

**For Questions regarding your DSCA report or to authenticate a subsequent transaction, please contact [SALES@GENTEKUSA.COM](mailto:SALES@GENTEKUSA.COM).**